IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION This Document Relates To: *All Actions*	Hon. Robert. B. Kugler Civ. No. 1:19-md-02875 (RBK/JS)

THIRD-PARTY PAYORS' OPPOSITION TO DEFENDANTS' JOINT MOTION TO EXCLUDE THE OPINIONS OF KALIOPI PANAGOS, PHARM.D., R.PH.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Rules

INTRODUCTION

Dr. Panagos is well qualified to offer the opinions in her October 2022 Report.[1] She has a bachelor's degree and a doctorate in pharmacy. She has over 20 years of experience in the pharmaceutical industry and is the Executive Vice President of ARMSRx Pharmacy Benefit Consulting, an organization that provides pharmacy benefits guidance to self-insured employers, brokers, and TPAs/TPPs. She has served on the faculty and administration of Long Island University's College of Pharmacy, and she has dedicated over ten years to the managed care and pharmacy consulting industry, overseeing clinical development, overall PBM operations, and client services/management, working primarily with TPAs and TPPs. And the Court has already found Dr. Panagos qualified to provide relevant background information to the jury and permitted more than fifty-four paragraphs of her opinions. Opinions on Certification of Proposed Classes FRCP 23 & Expert Reports FRE 702 at 94, Feb. 8, 2023, [D.E. 2261] (the "Order") (Dr. Panagos's "[o]pinions at paragraphs 1 to 46, 49-51 and 54 in her Report and in the Summary of Opinions on page 10, paragraphs: A, C, E, and F have been considered as suitable background.").

Yet, Defendants pretend that they are starting from a clean slate and argue that Dr. Panagos doesn't have good grounds for her opinions and that she isn't qualified to issue her opinions. But the Court's Order is the law of the case, and there is nothing that Defendants argue

[1] Expert Report of Kaliopi Panagos, Pharm.D., R.Ph., Oct. 31, 2022, [D.E. 2294-2] (the "October 2022 Report").

in their Motion[2] that would justify excluding sections of Dr. Panagos's October 2022 Report that the Court has already found to be admissible.[3]

Defendants mischaracterize Dr. Panagos's opinions to make them sound as specific and narrow as possible so they can then argue that Dr. Panagos doesn't have the particular expertise Defendants deem necessary. But that's of little import because "the Third Circuit [has] rejected the notion that an expert witness 'must actually have practical experience in a given industry in order to qualify as an expert in litigation involving its products.'" *Evans v. Imo Indus.*, *Inc*., 2019 WL 3253781, at *2 (D. Del. 2019) (citing *Trowbridge v. Abrasive Co. of Philadelphia*, 190 F.2d 825, 829 & n.9 (3d Cir. 1951)). And the Third Circuit has "reiterated its reluctance to require highly particularized, sub-specialization on the part of experts." *Knight v. Otis Elevator Co.*, 596 F.2d 84, 88 (3d Cir. 1979) (citing *Bundie v. Skil Corp.*, 591 F.2d 1334 (3d Cir. 1979)).

Defendants also argue that Dr. Panagos improperly opines on whether Defendants complied with applicable statutory and regulatory requirements. But "[t]he Third Circuit has permitted experts to opine on established industry customs and standards, provided the testimony stops short of defining the legal duties arising from industry customs or opining on whether the defendant has complied with those duties." *Mastripolito v. Jefferson Health-New Jersey*, 2022

[2] Mem. of Law in Supp. of Defs.' Joint Mot. to Exclude the Ops. of Kaliopi Panagos, Mar. 13, 2023, [D.E. 2294] (the "Motion").

[3] Relatedly, Defendants submitted a chart as an exhibit that purports to show opinions the Court already excluded. D.E. 2294-5. However, that exhibit doesn't accurately reflect the Court's rulings and fails to account for changes that Dr. Panagos made to her October 2022 Report.For example, the Court's Order **did not** exclude Summary Opinion J as restated in Summary Opinion XIV. of Dr. Panagos's October 2022 Report. However, footnote 1 of Defendants' chart incorrectly states that "[b]ased on the Court's reasoning as articulated in the February 8, 2023 opinion, [Defendants] believe Summary Op. J was inadvertently omitted from the list of excluded opinions." Additionally, Dr. Panagos's October 2022 Report makes no reference to the word "warranty." Plaintiffs further address this issue in Section III below.

WL 334169, at *2 (D.N.J. 2022) (citing *Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 218 (3d Cir. 2006)). That is all Dr. Panagos does here.

Finally, defendants argue that Dr. Panagos should be prohibited from offering opinions about ZHP on the notion that she doesn't have any opinions about ZHP in her October 2022 Report. Dr. Panagos's October 2022 Report shows otherwise.

LEGAL STANDARD

Under the Federal Rules of Evidence:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Waldorf v. Shuta, 142 F.3d 601, 625 (3d Cir. 1998) (quoting Fed. R. Evid. 702). "For a court to qualify a witness to testify as an expert, Rule 702 requires the witness to have 'specialized knowledge' regarding the area of testimony" and "[t]he basis of this specialized knowledge 'can be practical experience as well as academic training and credentials.'" *Id*. (quoting *American Tech. Resources v. United States*, 893 F.2d 651, 656 (3d Cir.1990)); *Daubert v. Merrell Dow Pharms., Inc*., 509 U.S. 579, 590 (1993) ("Proposed testimony must be supported by appropriate validation—i.e., good grounds, based on what is known.") (quotation marks omitted). The Third Circuit has "interpreted the specialized knowledge requirement liberally, and [has] stated that this policy of liberal admissibility of expert testimony 'extends to the substantive as well as the formal qualification of experts.'" *Waldorf*, 142 F.3d at 625 (quoting *In re Paoli R.R. Yard PCB Litig*., 35 F.3d 717, 741 (3d Cir. 1994)). The baseline requirement is simply that "a proffered expert witness . . . must possess skill or knowledge greater than the average layman." *Id*. (quotation marks omitted). "If the expert meets liberal minimum qualifications, then the level of

the expert's expertise goes to credibility and weight, not admissibility." *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 809 (3d Cir. 1997), *as amended* (Dec. 12, 1997).

ARGUMENT

I. DR. PANAGOS HAS GOOD GROUNDS FOR HER OPINIONS

Defendants argue that Dr. Panagos's opinions are unsupported on the theory that she has not established "good grounds" for her opinions on the notions that she (1) didn't test the RLD or the VCDs at issue for nitrosamines, (2) doesn't have "insight" into how SummaCare and Emblem specifically approved the VCDs at issues, and (3) doesn't have a basis for her FDA related opinions. But Defendants largely mischaracterize Dr. Panagos's actual opinions, which are well supported and based on her more than 20 years of experience working in the pharmaceutical industry and her experience working with TPP clients to place drugs on formularies.

A. Defendants Mischaracterize Dr. Panagos's Opinion Regarding the Equivalence of VCDs and the RLD

Defendants argue that Dr. Panagos "offers several opinions concerning the purported impact on 'equivalence' and 'sameness' between VCDs and the RLD due to the alleged presence of nitrosamine impurities in the former, but not the latter." Mot. at 9. According to Defendants, that opinion is unsupported on the theory that Dr. Panagos did "not bother to actually confirm – or even check whether the RLD was tested for – or ever contained impurities." *Id.* As Defendants see it, "Dr. Panagos simply assumes a fact that is essential to her conclusions: that the nitrosamine impurities were never in the RLD." *Id.*

But in making those arguments, Defendants misstate Dr. Panagos's opinion. When Dr. Panagos refers to the "RLD," she does not refer to a specific RLD pill that was manufactured and sold by the brand name manufacturer. Rather, she refers to the RLD manufacturers' FDA

applications and related documentation, which identify the ingredients and manufacturing process. This is plain from Dr. Panagos's opinion.

As Dr. Panagos states in her October 2022 Report, she intends to provide the jury with background information as to the process that P&T committees use to approve generic drugs for placement on a formulary. October 2022 Report at ¶ 1. The P&T committees consider the Orange Book, which identifies drugs that are equivalent. The Orange Book equivalency ratings are based on the generic VCD manufacturers' ANDA applications, in which, the manufacturers assert that the generic drugs are therapeutically equivalent to the RLD as approved by the FDA. *Id.* at ¶ 45, XII. There is no dispute that the RLD approved by the FDA never listed nitrosamines as an ingredient or part of the manufacturing process. As such, it is irrelevant whether a specific RLD pill may have contained nitrosamines. What matters is that the ANDA never identified nitrosamines as an ingredient or as part of the manufacturing process, so that the P&T committees would not have had any reason to believe that the generic VCDs contained nitrosamines.[4]

Defendants next argue that the Court has already ruled that Dr. Panagos cannot opine on "bioequivalence issues." Mot. at 17. But Defendants go too far in making that argument. In the Order, the Court excluded portions of Dr. Panagos's November 2021 Report[5] where she

[4] Defendants also argue that Dr. Panagos "never looked at the test results as to the level of NDMA and/or NDEA in individual VCDs," and that she therefore doesn't have good grounds to "support her various opinions that the alleged presence of nitrosamine impurities caused the generic VCDs to differ from the RLD." Mot. at 16. But that isn't the law. An expert doesn't have to do his or her own testing and may rely on testing done by others. Fed. R. Evid. 703 ("An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed."). Here, Dr. Panagos relied on the FDA's recall of the VCDs due to NDMA contamination. *See* October 2022 Report at ¶ 16.

[5] Expert Report of Kaliopi Panagos, Pharm.D., R.Ph., Nov. 21, 2021, [D.E. 2294-4] (the "November 2021 Report").

concluded that the bioequivalence formed part of a "warranty."[6] Order at 94 ("[p]reclud[ing] the opinions in Dr. Panagos's Report at paragraphs 47, 52-59 and in the Summary Opinions on page 10, paragraphs: B, D, G-I"). However, the Court *did* permit Dr. Panagos to opine on equivalency as background information for the jury to consider. *Id.* (permitting "[h]er opinions at paragraphs [43-46 and 50-51]"). That is all Dr. Panagos does here. *See* October 2022 Report at ¶¶ 80, 102, 105, V, and IX.

B. Dr. Panagos's Opinions Concerning the Formulary Decisions of SummaCare and Emblem are Well Supported

Defendants argue that Dr. Panagos's "opinions as to how SummaCare, Inc. and EmblemHealth *specifically* decided to include VCDs' on their drug formularies and reimburse for their purchase are purely speculative and unsupported" on the notion that Dr. Panagos didn't speak to a member of SummaCare's or Emblem's P&T committees, or review their deposition transcripts, and didn't read any board meeting minutes. Mot. at 19 (emphasis in original). Here, Defendants mischaracterize Dr. Panagos's expert opinion to make her sound like a fact witness, which she is not.

Dr. Panagos has no intention of telling the jury how SummaCare and Emblem "created their drug formularies or reimbursed for VCD purchases," as Defendants claim. Mot. at 18. That is a fact question that isn't the subject of expert testimony.[7] Rather, she intends to provide background information regarding industry standards and practice relating to the method by

[6] Dr. Panagos did not have the benefit of the Order when she drafted her October 2022 Report. Plaintiffs address Defendants' "warranty" arguments in Section III(B) below.

[7] What Defendants demand makes little sense. One does not need an expert with a doctorate in pharmacy to review P&T meeting minutes and deposition transcripts to regurgitate that information back to the jury. At trial, that evidence will be presented to the jury in the form of lay testimony or documentary evidence, Dr. Panagos will provide her general background testimony as to industry standards and customs, and the jury can determine what weight to ascribe to that evidence.

which P&T committees put together a drug formulary and reimburse for VCDs. That expert testimony will help the jury put in context the evidence specific to SummaCare and Emblem, which, as Defendants implicitly acknowledge, will likely consist of board meeting minutes and testimony by corporate representatives. *New York City Transit Auth. v. Express Scripts*, *Inc.*, 588 F. Supp. 3d 424, 444 (S.D.N.Y. 2022), *reconsideration denied*, 2022 WL 3577426 (S.D.N.Y. 2022) (the fact that expert had "worked only with '*other* PBMs who were operating under *different* contracts' . . . does not render her unqualified to speak on PBM industry standards and practices generally") (emphasis added); *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 2020 WL 6887885 (E.D. Pa. 2020) ("[T]he testimony of regulatory experts on the reasonableness of a pharmaceutical company's conduct in light of the complex nature of the FDA framework is helpful to a jury.") (citing *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 478-79 (S.D.N.Y. 2016)); *Bradley v. S.C. Boys*, *Inc.*, 2022 WL 3021140, at *3 (M.D. Pa. 2022) (permitting expert "to testify about the restaurant industry's standards and customs").

Defendants also criticize Dr. Panagos for relying on Plaintiffs' counsel's representations regarding the identity of the PBMs that SummaCare and Emblem use. Mot. at 18. But that is a non sequitur. None of Dr. Panagos's opinions turn on the specific identity of the PBMs that SummaCare and Emblem use—and even if they did, experts are permitted to rely on counsel's representations in forming their opinions. *Williams v. Illinois*, 567 U.S. 50, 67 (2012) (an expert witness can "voice an opinion based on facts concerning the events at issue even if the expert lacks first-hand knowledge of those facts").[8]

[8] Defendants' reliance on *MDG Int'l*, *Inc. v. Australian Gold*, *Inc.*, 2009 WL 1916728 (S.D. Ind. 2009) is misplaced. In *MDG*, the expert's *sole* basis for his damages opinion was counsel's

C. Dr. Panagos has a Strong Basis for her FDA-Related Opinions

Far from "unsupported speculation" as Defendants contend, Dr. Panagos's opinions on FDA guidance and processes are well supported by her experience in the industry and knowledge of the FDA's requirements. Mot. at 21. As such, her opinions should not be excluded.

1. *Dr. Panagos's Opinions on the ANDA Approval Process and the Duties of Generic Drug Manufacturers are Supported*

Defendants argue that Dr. Panagos's characterization of FDA regulations governing the ANDA approval process and manufacturers' compliance are not supported. Mot. at 21-22. Because Dr. Panagos's October 2022 Report does not include specific citations to the labyrinth of FDA regulations and the Code of Federal Regulations on this topic, Defendants argue that her opinions should be excluded. However, "[t]he Third Circuit has permitted experts to opine on established industry customs and standards, provided the testimony stops short of defining the legal duties arising from industry customs or opining on whether the defendant has complied with those duties." *Mastripolito*, 2022 WL 334169, at *2 (citing *Berckeley*, 455 F.3d at 218).[9] This is what Dr. Panagos has done. The law does not require her to provide legal citations.

Dr. Panagos opines on "established industry customs and standards," as articulated in *Mastripolito*, and she has stated the basis for her opinions. For example, Defendants take issue with a citation in a footnote to paragraph 46 of her October 2022 Report to an FDA webpage that links to the FDA's "Abbreviated New Drug Application (ANDA) Forms and Submission

representations. Here, Dr. Panagos's opinion is based on her more than 20 years working in the pharmaceutical industry, and her report is replete with citations to authority. Her reliance on counsel was minimal and on an issue that is of little consequence to her opinion.

[9] In *Berckeley*, the Third Circuit held that an expert in offshore securities transactions could testify about the "customs and business practices in the securities industry at the time the parties entered into the Agreement," as this could "provide[] an important context which will aid the jury in determining whether [appellee] had the requisite scienter at the time to evade the registration requirements." 455 F.3d at 218.

Requirements." When asked at her deposition about this, Dr. Panagos testified that the FDA "requirements" cited on the website did in fact provide the "basis" for her opinion that "[t]he supply chain must be solid and for approval of an ANDA, Good Manufacturing Practices and inspection reports are considered." Panagos Dep. 95:11-21, Jan. 11, 2023, [D.E. 2294-3].[10] Dr. Panagos further clarified that in addition to her "experience as a pharmacist for over 20 years in understanding how the supply chain works and what's required for a drug to be in compliance with these requirements," on the website she cited "[t]here are references to the ANDA forms, review, the electronic submission process, what that entails, [] by the FDA, formulation studies, summaries, regulatory resources, compliance/regulatory information." *Id.* at 99:25-100:5. Dr. Panagos made it a point at the deposition to state that she had "[p]oint[ed] out several areas within this reference where regulatory requirements, process, submission and references to the statement would be found and supported, in addition to my experience and over 20-plus years in -- as a clinical pharmacist, understanding how the supply chain works." *Id.* at 100:14-20.

Dr. Panagos may testify about "[t]he FDA drug approval process, FDA regulations, and protocols of drug labeling," because these are "[t]opics that are likely unfamiliar to a layperson, and expert testimony on these topics will be helpful to the jury's understanding of the complex issues in this case." *In re: Tylenol (Acetaminophen) Mktg., Sales Pracs., & Prod. Liab. Litig.*, 2016 WL 4039271, at *8-9 (E.D. Pa. 2016) (citation omitted). Dr. Panagos is neither offering

[10] Q. In paragraph 46 you provide a footnote number 6, referencing a page of the FDA website; correct?
A. Correct.
Q. Does that mean that that particular page provides the basis for your statement that the supply chain must be solid, and for approval of an ANDA, Good Manufacturing Practices and inspection reports are considered?
A. Correct.
Panagos Dep. 95:11-21, Jan. 11, 2023.

legal or regulatory opinions, nor opinions on a particular manufacturer's compliance with applicable FDA regulations. Instead, she is explaining *why* the ANDA approval process exists, what it entails, and why the supply chain needs to be solid.[11] This is permissible expert testimony that is supported by Dr. Panagos's experience and knowledge of the FDA's requirements.

2. *Dr. Panagos's Opinions Concerning Medication Guides are Supported*

Defendants argue that Dr. Panagos does not have a basis for her opinions because Medication Guides are not applicable to VCDs. Mot. at 24-26. While it is true that the FDA does not require that VCD medications have a Medication Guide, they are appropriate when additional details could be crucial to the safe use or effectiveness of a particular medication, such as preventing serious adverse effects. In the case of the VCDs, the contaminant rendered the generic *not the same* as the RLD. Thus, it was the presence of the contaminant, a known human carcinogen, that posed a danger to humans, and why the Medication Guide should have been provided.

To that end, Defendants showed Dr. Panagos an exhibit at her deposition entitled "Why do some medicines have Medication Guides?" that was prepared by the FDA. Panagos Dep. Ex. 12 at 1, Jan. 11, 2023. According to Defendants' exhibit, the "FDA requires that Medication Guides be issued with certain prescribed drugs and biological products when the Agency determines that:

- certain information is necessary to prevent serious adverse effects
- patient decision-making should be informed by information about a known serious side effect with a product, or

[11] Panagos Dep. at 97:17-23, Jan. 11, 2023 ("As a pharmacist, knowledge of a supply chain that is producing solid, safe and effective medications that – in compliance with Good Manufacturing Practices is -- it's key, is pertinent, is absolutely necessary. There is no deviation from that.").

- patient adherence to directions for the use of a product are essential to its effectiveness."

Id. Certainly the inclusion of NDMA or NDEA in VCDs and their corresponding side effects would be "information [] necessary to prevent serious adverse effects." *Id.* Dr. Panagos's opinions about Medication Guides are thus supported and grounded in her years of experience as a clinical pharmacist. *See* Panagos Dep. 177:23-178:13, Jan. 11, 2023.[12]

In sum, Dr. Panagos provides a basis for all her enumerated FDA-related opinions and they should not be excluded.

D. Dr. Panagos's Opinions are Reliable and Should not be Excluded

Defendants argue that Dr. Panagos fails to provide support for her opinions and "often broadly relied on her background, education, and experience, as well as the entirety of the reliance list appended to the 10/31/22 Report." Mot. at 26. Because Dr. Panagos's expertise is based on her "practical experience, rather than academic theories," it is no surprise that the *Daubert* reliability inquiry must focus on her "knowledge and experience . . . rather than the methodology or theory behind it." *States v. Fernwood Hotel & Resort*, 2014 WL 198568, at *3, *4 (M.D. Pa. 2014) (examining a proposed expert's qualifications "because [the expert's] opinion is based solely on his experience," and finding that "[h]is years of experience and relevant expertise provide the necessary support for his opinions") (citation omitted); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("[T]he relevant reliability concerns may focus upon personal knowledge or experience.").

[12] "I've been a pharmacist a long time, and requirement or not, it is always advisable for the patient to be informed of their medication. We've all been to the pharmacy. We want to know what we're taking and we want to know about our drug, and we certainly want to know if it's safe and effective and we absolutely want to know if there's a carcinogen to it. And when it comes to a generic, we want to trust that that generic is equivalent, same as the brand. Requirement or not, those are the expectations." Panagos Dep. 177:23-178:13, Jan. 11, 2023.

Dr. Panagos's opinion is well supported by her more than 20 years of experience in managed care and the pharmacy consulting industry, including overseeing clinical development and overall PBM operations, and working with TPAs and TPPs. Courts routinely find that an expert's opinion can be "supported" based on their "*extensive and specialized experience*." *Hendricks v. Ford Motor Co.*, 2012 WL 12045429, at *3 (E.D. Tex. 2012). In *Hendricks*, the court explained that "[the] witness' experience, studies and education, combined with a review of the relevant materials can provide a reliable basis for expert testimony." *Id.* The court in *United States v. Lawson* found the expert's opinion supported by her resume, which showed she had "ten years of experience auditing financial documents, ke[pt] up with continuing professional education, and ha[d] an appropriate educational background for auditing." 2009 WL 1208014, at *5-6 (E.D. Ky. 2009). And in *Fox v. Makarchuk*, the court found that "***experience alone***—or experience in conjunction with other knowledge, skill, training or education" could provide sufficient support for the expert's opinion. 2021 WL 4146907, at *4 (D. Wyo. 2021) (emphasis added).

Defendants point to a question Dr. Panagos was asked at her deposition regarding the basis for paragraph 18 of her October 2022 Report, which states "[a]nimal studies have found that NDMA caused liver and lung cancer, as well as other cancers such as esophageal cancer, bladder cancer, gastric cancer, colorectal cancer and others", Mot. at 27, and she testified it was from the IARC information. Panagos Dep. at 76:21-77:5, Jan. 11, 2023. Contrary to Defendants' suggestion, Dr. Panagos need not have a background in pathology or oncology to rely on information provided by the IARC to form her opinion. *See JQ Adams & Sons, Inc. v. Scottsdale Ins. Co.*, 2022 WL 2643587, at *8 (M.D. Fla. 2022) ("[A]n expert is permitted wide latitude to

offer opinions, including those that are not based on firsthand knowledge or observation.") (citing *Daubert*, 509 U.S. at 592).

Next, Defendants suggest that the citations (or lack thereof) and website links contained in paragraphs 37, 46, and 70(b)[13] of Dr. Panagos's October 2022 Report are mere "*ipse dixit* of the expert" and should be excluded. Mot. at 28. However, the contested citations were not to specific articles or factual claims, but to foundational principles and examples that assisted Dr. Panagos in formulating her opinions rendered in those paragraphs. *See*, *e.g.*, *In re Mirena*, 169 F. Supp. 3d at 420 ("[L]ack of specific citation in [expert's] report goes to the weight of her opinions, not their admissibility."); *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4582209, at *3 (S.D.W. Va. 2016) ("As to the opinions that are not accompanied by citations, I am not convinced that the lack of copious citations renders an opinion unreliable."); *O'Bryant v. Johnson & Johnson*, 2022 WL 7670296, at *11 (D.N.J. 2022) ("The Court recognizes Defendants' other concerns with the lack of citations offered by Dr. Garely, but Defendants are free to cross-examine Dr. Garely about these issues at trial.").

Thus, Dr. Panagos's opinions are reliable and should not be excluded.

[13] Defendants take issue with paragraph 70(b) of the October 2022 Report as to the lack of a citations arguing that "the information within that parenthetical is nowhere to be found in the source upon which Dr. Panagos relies for this paragraph." Mot. at 28. However, Dr. Panagos made clear *where* the information she was relying on for this statement was coming from. *See* Panagos Dep. at 124:24-125:9, Jan. 11, 2023 ("As I said earlier, *the information is from my sources, in the appendix which is provided here, including my experience, education and background*. And while that isn't explicitly in this source right here that you – in Exhibit 10 that you presented, part of the ANDA process includes demonstrating safety and effectiveness. That is without dispute and without doubt part of that process.") (emphasis added).

II. DR. PANAGOS IS QUALIFIED TO RENDER HER EXPERT OPINIONS

Dr. Panagos has a bachelor's degree and a doctorate in pharmacy. She has over 20 years of experience in the pharmaceutical industry[14] and is the Executive Vice President of ARMSRx Pharmacy Benefit Consulting, an organization that provides pharmacy benefits guidance to self-insured employers, brokers, and TPAs/TPPs. October 2022 Report at ¶ 7. She has served on the faculty and administration of Long Island University's College of Pharmacy, and she has dedicated over ten years to the managed care and pharmacy consulting industry, overseeing clinical development, overall PBM operations, and client services/management, working primarily with TPAs and TPPs. *Id.* at ¶ 9-10.

Despite that extensive background and experience, Defendants repeatedly argue that Dr. Panagos isn't "qualified" to offer the opinions in her reports. Those arguments follow the following predictable pattern. First, Defendants mischaracterize Dr. Panagos's opinion and try to make it sound as specific and narrow as possible. Then, they assert that Dr. Panagos could only be an expert in that specific and narrow field if she had prior expertise working in that precise field. And finally, they argue that Dr. Panagos isn't qualified because she purportedly doesn't have the particular expertise Defendants deem necessary.

But none of that gets Defendants very far, as "the Third Circuit [has] rejected the notion that an expert witness 'must actually have practical experience in a given industry in order to qualify as an expert in litigation involving its products.'" *Evans*, 2019 WL 3253781, at *2 (citing

[14] *See* Panagos Dep. 99:25, 100:2-7, Jan. 11, 2023 ("[She has] experience as a pharmacist for way over 20 years in understanding how the supply chain works and what's required for a drug to be in compliance with *these* requirements in order to be available for prescribers to prescribe."); *Id.* at 117:10-14 ("[Dr. Panagos's] many years of experience and [Dr. Panagos's] communication and collaboration . . . with how P&T committees work, PBMs, their processes and how formulary decisions are made.").

Trowbridge, 190 F.2d at 829 & n.9). In fact, the Third Circuit has "reiterated its reluctance to require highly particularized, sub-specialization on the part of experts." *Knight*, 596 F.2d at 88 (citing *Bundie*, 591 F.2d at 1334).

Unsurprisingly, there is an extensive line of cases finding experts qualified despite not having experience in a specific field. *Knight*, 596 F.2d at 88 (overturning the district court and finding an expert qualified to testify that "unguarded elevator control buttons . . . constituted a design defect in the construction and installation of said elevator" even though the expert didn't have a "background in the design and manufacture of elevators"); *Evans*, 2019 WL 5457101, at *7-8 (expert qualified to testify about "the United States Navy's purchase and procurement of the products" because while "he lack[ed] direct experience in ordering parts for Navy ships," he was "familiar with the process as a result of participating in "hundreds of meetings to discuss procurement issues"); *Sioux Steel Co. v. Prairie Land Mill Wright Servs.*, 2022 WL 17184469, at *4 (N.D. Ill. 2022) (expert qualified "to opine on infringement" related to bin sweeps because "[a]lthough he is not experienced with the design of grain bin sweeps, he holds a degree in engineering and his 'technical background is sufficiently related to that pertinent art'"); *George v. Morgan Const. Co.*, 389 F. Supp. 253, 259 (E.D. Pa. 1975) (expert qualified to give an "opinion about the guarding of the Fairless bar mill" even though he "admittedly lacked expertise in the design and operation of bar mills"). Any purported concerns about the specificity of Dr. Panagos's experience "should go to the weight, and not to the admissibility, of [the expert's] opinion." *Knight*, 596 F.2d at 88.

As shown above, Dr. Panagos has a broad and deep knowledge of the pharmaceutical industry and the process by which P&T committees approve generic drugs. She is plainly qualified to testify about the entirety of that process and the relevant considerations for P&T

committees. This is especially true when one considers that the Court has already deemed Dr. Panagos qualified to render many of the very same opinions that Defendants challenge here, and "the law of the case doctrine limits relitigation of an issue once it has been decided in an earlier stage of the same litigation." *Hamilton v. Leavy*, 322 F.3d 776, 786 (3d Cir. 2003) (citation and quotation marks omitted). Plaintiffs attach as Exhibit A a chart comparing the opinions the Court previously deemed admitted with Dr. Panagos's October 2022 Report.

A. Dr. Panagos's Opinions that Touch on the FDA Approval Process

Defendants claim that Dr. Panagos "offers multiple opinions on FDA-related issues, including Medication Guides, the regulatory application process by which generic drugs are reviewed and approved by the FDA (ANDAs), and manufacturers' duties with respect to the ANDA process." Mot. at 29. They then argue that Dr. Pangos is "plainly unqualified to offer any of those opinions" because she has no "experience in regulatory affairs" either "on behalf of the FDA or a generic manufacturer." *Id.* at 29, 31. Defendants' arguments are unfounded.

Dr. Panagos opinions on the FDA issues in her reports provide background information on some considerations that are relevant to P&T committees. As explained above, there is no requirement that Dr. Panagos have obtained her expertise in a certain manner as suggested by Defendants when they argue that she never "work[ed] with any of [those] issues, either on behalf of the FDA or a generic manufacturer." *Knight*, 596 F.2d at 88; *Evans*, 2019 WL 5457101, at *7-8; *Sioux*, 2022 WL 17184469, at *4; *George*, 389 F. Supp. at 259. Dr. Panagos's experience as a pharmacist and her work with P&T committees qualifies her to opine on those issues. *See*

discussion *supra* Section II (highlighting Dr. Panagos's relevant experience). Indeed, the Court has already found Dr. Panagos is qualified to opine on these issues.[15]

B. Dr. Panagos's Opinions on the Type of Information that TPPs Rely on When Considering Generic Drugs for Formulary Inclusion and Reimbursement

Defendants argue that Dr. Panagos isn't qualified to offer opinions as to "[h]ow TPPs and P&T committees generally determine formulary drug inclusion and reimbursement" on the theory that she doesn't have "[s]ufficient experience creating drug formularies or reimbursing for purchases of the drugs." Mot. at 31-32 (emphasis original). According to Defendants, Dr. Panagos (1) in her role as a pharmacy benefit consultant only "works *with* clients that create and manage drug formularies," but "*she* does not create and manage drug formularies", (2) "[h]as only *once* in her career held a role where she directly created and managed formularies", and (3) "[h]as never served as a member on a P&T Committee" or "[w]orked for a TPP." *Id.* at 31-32 (emphasis in original).

But as shown in Section II(A), there is no rule that requires an expert to obtain his or her experience in a specific way, as Defendants assert. *Knight*, 596 F.2d at 88; *Evans*, 2019 WL 5457101, at *7-8; *Sioux*, 2022 WL 17184469, at *4; *George*, 389 F. Supp. at 259. Dr. Panagos has years of experience working with P&T committees on placing drugs on formularies[16] and she has directly managed drug formularies. *See* discussion *supra* Section II (highlighting Dr.

[15] Order at 94 (Dr. Panagos's "[o]pinions at paragraphs . . . [29] to 46, 49-51 and 54 in her Report and in the Summary of Opinions on page 10, paragraphs: A, C, E, and F have been considered as suitable background.").

[16] *See*, *e.g.*, Panagos Dep. at 41:2-24, Jan. 21, 2022, [D.E. 2294-9]; Panagos Dep. at 57:9-13, Jan. 11, 2023; Panagos Dep. at 88:24-89:20, Jan. 21, 2022.

Panagos's relevant experience). And, the Court has already found Dr. Panagos is qualified to issue these opinions.[17]

C. Dr. Panagos's Opinions Regarding the Orange Book

Defendants argue that Dr. Panagos's "[g]eneral familiarity with the Orange Book does not qualify her as an expert to opine on the *specific* process by which a drug is included in the Orange Book" on the notion that she "[h]as never been involved with the decision to include a drug in the Orange Book." Mot. at 32 (citation omitted). But as shown above in Section II, there is no rule that requires an expert to obtain his or her experience in a specific way. *Knight*, 596 F.2d at 88; *Evans*, 2019 WL 5457101, at *7-8; *Sioux*, 2022 WL 17184469, at *4; *George*, 389 F. Supp. at 259. Dr. Panagos is qualified to opine on the Orange Book and the role it plays in approving generic drugs on a formulary. She has more than 20 years of experience in managed care and the pharmacy consulting industry, where she oversaw clinical development and overall PBM operations and worked with TPAs and TPPs regarding formulary management. *See* discussion *supra* Section II (highlighting Dr. Panagos's relevant experience). And the Court has already found Dr. Panagos is qualified to testify about the Orange Book.[18]

Nonplussed, Defendants argue that Dr. Panagos's "[t]estimony directly contradicts *what the Orange Book itself says* about what the inclusion of a drug does and does not mean" which they claim highlights "her utter lack of knowledge and qualifications to opine on the subject." Mot. at 32-33 (emphasis in original). As a basis for this bold assertion, Defendants point to three lines from her deposition, where she testified "if there was a deviation from therapeutic

[17] Order at 94 (Dr. Panagos's "[o]pinions at paragraphs . . . [21 to 28,] . . . [44] to 46, 49-51 and 54 in her Report and in the Summary of Opinion[] on page 10, paragraph[] . . . E . . . ha[s] been considered as suitable background.").
[18] *Id.* (Dr. Panagos's "[o]pinions at paragraphs . . . [29 to 32] . . . in her Report and in the Summary of Opinion[] on page 10, paragraph[] . . . F ha[s] been considered as suitable background.").

equivalence, the drug would absolutely not be in the Orange Book." Mot. at 32. According to Defendants, that cherrypicked quote is at odds with the preface to the Orange Book, which states "[i]nclusion of products in the Orange Book is independent of any current regulatory action being taken administratively or judicially against a drug product." Mot. at 33 (citation omitted).

But there is no contradiction. As shown in Section I, when Dr. Panagos opines on the equivalency between the RLD and the generic, she refers to the RLD as set out in the manufacturers' FDA applications and related documentation, which identify the ingredients and manufacturing process—not a specific pill that was manufactured by the RLD manufacturer. And that fits perfectly with the explanation in the Orange Book's preface that "[i]nclusion of products in the Orange Book is independent of any current regulatory action being taken administratively or judicially against a drug product."

In any event, Defendants' challenges go to the weight of Dr. Panagos's opinions and are not a basis to disqualify her under *Daubert*. *See Fox v. Dannenberg*, 906 F.2d 1253, 1256 (8th Cir. 1990) ("Once the trial court has determined that a witness is competent to testify as an expert, challenges to the expert's skill or knowledge go to the weight to be accorded the expert testimony rather than to its admissibility.") (citations omitted); *Campbell v. Fawber*, 975 F. Supp. 2d 485, 500 (M.D. Pa. 2013) ("[C]hallenges [to] the accuracy of [an expert's] conclusions goes to the weight of the evidence rather than its admissibility" and can be explored on cross-examination.) (citation omitted).

III. DR. PANAGOS MAY TESTIFY ABOUT GENERAL CUSTOMS, STANDARDS, AND PRACTICES IN THE PHARMACEUTICAL INDUSTRY

Defendants seek to exclude certain opinions by Dr. Panagos, which they characterize as "opinions concerning whether Defendants complied with applicable statutory and regulatory requirements." Mot. at 28. According to Defendants, these opinions should be excluded because

they are "no more than Dr. Panagos' belief as to 'whether Defendant[s] w[ere] in regulatory compliance with the FDA,'" which make the opinions "impermissible legal conclusions" that "must be excluded." *Id*.

"The Third Circuit has permitted experts to opine on established industry customs and standards, provided the testimony stops short of defining the legal duties arising from industry customs or opining on whether the defendant has complied with those duties." *Mastripolito*, 2022 WL 334169, at *2 (citation and quotation marks omitted). Dr. Panagos will not testify about whether Defendants have complied with their legal duties, but on general industry customs and standards. These are proper subjects for expert testimony. *Id.*; *In re: Tylenol*, 2016 WL 4039324, at *3 ("[A]n expert may offer testimony about business or trade customs and practices without invading the province of the court."); *In re Suboxone*, 2020 WL 6887885, at *45 ("[C]ourts have repeatedly allowed FDA regulatory experts to testify regarding regulatory requirements under the FDA.").

"An opinion is not objectionable just because it embraces an ultimate issue." Fed. R. Evid. 704(a). That does not mean an expert may "merely tell the jury what result to reach." *Krys v. Aaron*, 112 F. Supp. 3d 181, 192 (D.N.J. 2015) (quotation marks omitted). But while "an expert may not render any ultimate opinion concerning, for example, whether a specific party had capacity to make a will," they "may offer an opinion concerning whether that party had sufficient mental capacity to know the nature and extent of his property and the natural objects of his bounty and to formulate a rational scheme of distribution." *Id*. at 192-93 (quotation marks omitted). "In other words, under Rule 704, an expert may not make a conclusory statement on a party's capacity, but may provide testimony that touches the underlying issues relevant to a determination of capacity." *Id*. at 193. An expert "may provide an opinion on whether a party's

conduct or actions meet the underlying bases for an ultimate issue in a case," so long as they do not "merely instruct the jury on the result to reach based upon a party's specific conduct or actions (by, for example, stating that a party did indeed violate an applicable duty through certain actions)." *Id.*; *see also United States v. Xue*, 2022 WL 1027634, at *12-13 (E.D. Pa. 2022) (government's expert witnesses could not use legal term of art "trade secrets," but could testify "that the information at issue was confidential or proprietary information, that the information has economic value in the industry, and that steps are taken by GSK and other companies to preserve or keep confidential this information," and about "customs and practices in the biopharmaceutical industry," so long as the term "trade secrets" was not used).

Some of Dr. Panagos's opinions in her October 2022 Report are similar to opinions the Court excluded in its Order because it viewed them as opinions on legal questions that should be decided by the factfinder. Others, however, are not legal conclusions about the facts of this case but offer useful background information about how things work generally in the pharmaceutical industry and what categories of information P&T committees rely on when making decisions about the placement of drugs on formularies. Falling into this category of permissible opinions are opinions I, III, IV, V, VI, and IX.[19] These opinions speak generally about hypothetical

[19] *See* October 2022 Report at 24-25 ("I. The safety of a medication must be proven by the manufacturer to the FDA so that the medication may receive approval. This information serves as an assurance that the medication meets the quality standards outlined by FDA.), ("III. Manufacturers have ultimate responsibility for their quality process, manufacturing practices, safety obligations and all of the information presented in the ANDA which is reported to the FDA to obtain approval."), ("IV. If the generic manufacturer product changes in any way from the original product on the ANDA approval, then this changed product is not the same as the brand name medication (RLD) . . . . V. [In that event,] [t]he generic drug label, insert, and pamphlets are no longer accurate insofar as the generic manufacturers are not meeting the obligations required by the regulations; the changed product cannot be deemed safe or effective and equivalence is nulled; and the generic manufacturer may no longer rely on the RLD."), ("VI. TPPs, PBMs and P&T committees rely on the FDA approval as the indicator that the medication may be considered

situations that are common in the industry; they do not tell the jury what to decide on the facts here. It is simply wrong to describe these opinions, as Defendants do, as expressing "no more than Dr. Panagos's belief as to 'whether Defendant[s] w[ere] in regulatory compliance with the FDA,'" or as drawing "impermissible legal conclusions" about the facts of this case. Mot. at 35 (citation omitted).

The Court excluded opinions in Dr. Panagos's November 2021 Report where she said (as summarized by the Court) that "an Orange Book TE code on a generic drug expresses a warranty from the generic's manufacturer . . . to TPPs and P&T committees (agents that aid TPPs in developing drug formularies) that the generic is equivalent to the RLD." Order at 94. The Court reasoned that "whether TE codes and subcodes constitute a *warranty* is a legal question to be posed to, and answered by, the factfinder." *Id*. (emphasis added). Defendants now argue that Dr. Panagos's October 2022 Report "merely tell[s] the jury what result to reach" on their claims. Mot. at 37 (citation omitted).

Dr. Panagos's October 2022 Report addresses the Court's concern about the legal term "warranty" by replacing it with the more colloquial "assurance" and "representation", which are terms that do not appear in the elements of Plaintiffs' claims as the word "warranty" does. October 2022 Report at ¶ 80 ("A drug's 'AB' listing in the Orange Book, based as it is on the generic drug manufacturer's ANDA, represents a manufacturer's *assurance* to TPPs and P&T

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for formulary placement and plan coverage/reimbursement."), ("VII. The Orange Book lists the FDA approved generics of the original brands. The pharmaceutical industry, including TPPs, are meant to be able, by design, to rely on the information in the Orange Book such that these FDA approved generics can be put on a prescription drug formulary and/or plan coverage for reimbursement."), ("IX. PBMs establish formularies for generics based on the FDA approval process, and the information within the Orange Book tying these generics to their RLDs with the expectation that they are the same and/or therapeutically equivalent to the RLDs. TPPs reimbursed for these VCDs based on the assurances provided by the manufacturer in seeking approval and marketing the generics under the approved ANDA.").

committees that the generic drug is equivalent to the brand drug for placement on a prescription drug formulary.") (emphasis added); *Id.* at ¶ 102 ("When third party payors agree to reimburse for generic drugs such as valsartan including VCDs, they do so based on *representations* made by manufacturers that their drug product is in compliance with the FDA, bioequivalent of the Orange Book reference drug and safe to be sold to consumers.") (emphasis added); *Id.* at ¶ 103 ("In the case of valsartan, including VCDs, the *representations* made by the manufacturers were false. As such, TPPs paid for medications they should not have paid for. In fact, these VCDs never could have been sold in the United States.") (emphasis added).

Unlike the concern raised with using the word "warranty" when a case includes claims for breach of warranty, no such concern arises with using the words "assurance" or "representation" to describe the categories of information P&T committees rely on in making their decisions or the general nature of that reliance.

Also admissible are two paragraphs where Dr. Panagos describes information P&T committees typically rely on, but without getting into what happened in this case or telling the jury what it should find in this case. October 2022 Report at ¶ 99 ("P&T committees and TPPs rely on an Orange Book listing that a manufacturer's compliance means their drugs meet FDA regulations and as such are suitable for formulary placement and reimbursable under a prescription drug benefit plan."); *Id.* at ¶ 104 ("TPPs are entitled to rely on a manufacturer's compliance with Orange Book standards when reimbursing for what was represented as generic valsartan, including VCDs."). This is "background testimony" that "could be helpful to the jury." *Berckeley*, 455 F.3d at 218. While an expert cannot "opine that the Defendants breached their legal duties," they may testify about "[t]he FDA drug approval process, FDA regulations, and protocols of drug labeling" because these are "topics that are likely unfamiliar to a layperson,

and expert testimony on these topics will be helpful to the jury's understanding of the complex issues in this case." *In re: Tylenol*, 2016 WL 4039271, at *8-9 (quotation marks omitted); *Stanley v. Novartis Pharms. Corp*., 2014 WL 12573393, at *4 (C.D. Cal. 2014) ("[T]he Court finds that Dr. Parisian is qualified to and may testify generally regarding FDA regulatory scheme and requirements for pharmaceutical drugs."); *Patrick v. Moorman*, 536 F. App'x 255, 258 (3d Cir. 2013) (Experts are prohibited from "opining about the ultimate legal conclusion or about the law or legal standards," but "Rule 704 allows experts to provide an opinion about the 'ultimate issue' in a case.").

According to Defendants, "Dr. Panagos concedes that her 'assurance' and 'representation'-based opinions are warranty-based opinions dressed up in different clothing." Mot. at 38. That mischaracterizes Dr. Panagos's testimony. She did not say her opinions were "warranty-based," but that "assurance" and "warranty" both just mean "promise" or validation of sameness:

> "[a]ssurance or warranty, they really mean the same thing. It's the promise that the manufacturers make, validation that their product is identical to the brand product . . . ."

Panagos Dep. at 140:23-141:3, Jan. 11, 2023. She explained that she "made the change quite simply to make it in simpler language" because "I'm not a lawyer, I'm a clinical pharmacist, and what I'm relaying is that the manufacturers make promises, assurances ensuring that their drug is equivalent to the brand drug." *Id*. at 140:12-17. While it is possible that the jury could have been misled if Dr. Panagos had used the legal term "warranty" to convey the concept of a promise that one drug is equivalent to another, her replacement of that legal term with "assurances" removes any such concern.

In sum, Dr. Panagos's testimony does not "instruct the jury on the result to reach" on any of Plaintiffs' claims. *Krys*, 112 F. Supp. 3d at 193. It does bear on whether Defendants' "conduct or actions meet the underlying bases for an ultimate issue in a case", *Krys*, 112 F. Supp. 3d at 193, which is permissible expert testimony. *See Orner v. Nat'l Beef Packaging Co.*, *LLC*, 2015 WL 8334544, at *7 (M.D. Pa. 2015) ("[A]n expert may offer his opinion as to facts that, if found, would support a conclusion that the legal standard at issue was satisfied, but he may not testify as to whether the legal standard has been satisfied.") (citation omitted).

IV. DR. PANAGOS'S REPORT CLEARLY OPINES ABOUT ZHP AS AN API MANUFACTURER

Defendants argue that Dr. Panagos should be prohibited from offering opinions about ZHP because such opinions are not included in her October 2022 Report. Mot. at 40. Defendants' attempts to confuse Dr. Panagos during her deposition do not eliminate her opinions in her expert report, which clearly pertain to both the finished dose and API manufacturers, including ZHP. Dr. Panagos's October 2022 Report contains substantive discussion of ZHP's conduct, including whether it complied with cGMPs and whether its API conformed to regulatory standards. Paragraph 20 of Panagos's October 2022 Report states:

> The term TPPs generally refers to entities (other than the patient or health care provider) that reimburse and manage healthcare expenses including prescription drug benefits or coverage. It is my understanding that the Court will conduct a trial which will involve purchases paid for by SummaCare, Inc. ("SummaCare") and EmblemHealth ("Emblem"), both of which are TPPs. These TPPs, as with most TPPs, both included generic VCDs on their drug formularies and reimbursed for purchases of these VCDs (intended for personal or household use). Many of these VCDs were manufactured, distributed, or sold by **active pharmaceutical ingredient** and finished dose manufacturers**, including the relevant defendants here, Zhejiang Huahai Pharmaceuticals ("ZHP")**, Teva Pharmaceuticals and Torrent Pharmaceuticals.

October 2022 Report at ¶ 20 (emphasis added). Dr. Panagos also cites to the FDA's November 29, 2018 Warning Letter to ZHP, which summarizes "significant deviations from current good

manufacturing practice (CGMP) for active pharmaceutical ingredients (API),” in her list of materials reviewed. October 2022 Report App. A at 30.

Despite defense counsel’s attempts to confuse Dr. Panagos, she specifically identified ZHP as a defendant within the scope of her October 2022 Report during her deposition. In response to the question of whether she was offering any “opinions specifically regarding ZHP’s compliance with CGMP as an API manufacturer,” Dr. Panagos responded “among the Defendants here is ZHP.” Panagos Dep. 193:23-194:5, Jan. 11, 2023. As Defendants note, Dr. Panagos testified that she was offering opinions as to all manufacturers, including API manufacturers, pointing defense counsel to paragraph 20 of her October 2022 Report, which specifically cites API manufacturers and ZHP as “relevant Defendants.” *See id.* at 199:17-203:2.

Dr. Panagos’s October 2022 Report specifically references ZHP, and the opinions in her report expressly apply to all Defendant API manufacturers. Her deposition testimony confirms this. Therefore, Dr. Panagos should not be prohibited from offering opinions about ZHP’s conduct.

CONCLUSION

For the good reasons stated above, the Court should deny Defendants’ Motion to exclude Dr. Panagos’s expert report. She is more than qualified to offer her opinions and they are well supported by her more than 20 years of experience working in the pharmaceutical industry.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 11th day of April 2023, I caused a true and correct copy of the foregoing to be filed and served upon all counsel of record by operation of the Court's CM/ECF system.

/s/ *Jorge Mestre*